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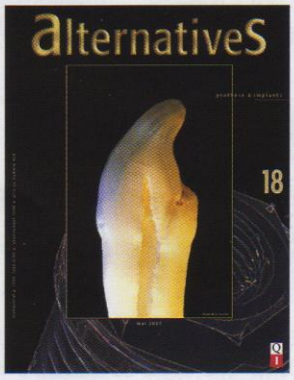

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Presentation of a gel designed for patients with removable dentures*

The iatrogenic action of conventional removable dentures results in damage to the support tissues leading to denture stomatitis. This can be particularly serious in elderly patients, in whom the impaired general state can decrease their capacity for adaptation. The new concept of a specific product designed for these patients appears to be particularly interesting. A preliminary study on a sample of totally edentulous patients with removable dentures of various ages and presenting with various states of health, possibly suffering from denture stomatitis, demonstrates the efficacy and relevance of using a oxygenated glycerol triester gel for the great majority of these patients. Application of this gel contributes to daily maintenance of the mucous membranes and facilitates the wearing and integration of dentures.

Denture stomatitis[3, 4, 6-11]

Removable dentures can cause mechanical irritation induced by the occlusal load and the inevitable friction between the base of the denture and the mucosa.
The fibromucosa gradually becomes irritated and presents signs of chronic inflammation, called denture stomatitis.
Denture stomatitis affects 50% of patients with complete removable dentures, especially involving the maxilla. It is associated with cheilitis or glossitis in 20% to 30% of cases.
The aggravating aetiological factor of this denture stomatitis is the presence of microorganisms in the denture lining. This infection is essentially due to colonization by *Candida albicans*.

According to some authors, such as Budtz-Jørgensen (1990), Davenport (1970), Renner[7] (1979), denture stomatitis is Candida-related: *Candida albicans* is a saprophytic organism which becomes pathogenic as a result of an imbalance of the oral flora, following the fitting of dentures. According to Walter[7] (1985), *Candida albicans* is an opportunistic organism which takes advantage of pre-existing inflammation to proliferate. Regardless of the *Candida* or bacterial aetiology, the denture is responsible for modifying the oral environment.

The studies by Kleinfinger[7] (1971) showed that the salivary pH decreases in totally edentulous subjects fitted with dentures (6.23), promoting the growth of *Candida albicans*. This denture-induced acidosis promotes the proliferation of *Candida*, decreases salivary flow and alters the quality of the saliva.

Apart from the presence of dentures, a poor general state, poor oral hygiene and xerostomia, an adverse effect of sedative drugs, can increase the risk of candidiasis in some patients, particularly elderly patients.

* Clinical study performed on patients with complete removable dentures

Paradoxically, regardless of the severity and extent of the lesions, denture stomatitis may remain undiagnosed in the majority of patients. They rarely complain of acute pain, but tend to describe discomfort. In fact, there are several clinical forms of denture stomatitis and a number of authors have proposed a classification. We will adopt the Budtz-Jørgensen classification (1974), based on the classification proposed by Newton[7] (1962).

Budtz-Jørgensen classification:

Type 1 (simple localized inflammation): The palatine mucosa presents red spots related to the orifices of mucous glands. Localized inflammatory zones are observed. The rest of the mucosa has a normal clinical appearance. The central region of the palate appears to be more frequently affected (Fig. 2).

Type 2 (simple diffuse inflammation): Inflammation affects almost all of the palatine mucosa. The mucosa over the denture has an erythematous, oedematous, satiny clinical appearance (Fig. 3).

Type 3 (*inflammatory papillary hyperplasia*): The palate, especially the central part, shows hyperplastic inflammatory formations, which can form papillae, 2 to 5 mm wide at the base. This form is described as granular or papillary (Fig. 4).

Oxygenated glycerol triesters

The properties of oxygenated glycerol triesters (OGT) have been demonstrated in the skin (dermis and epidermis):

- cell regeneration *in vitro* (Thomas J. Stephens – Dallas 1998),
- skin moisturization (Institut ASTER – France 1993),
- renewal of the epidermis and cutaneous biomechanical properties[12] (Dermscan – Lyon 1994),
- improvement of tissue perfusion with applied pressure[12] ($TcpO_2$; Colin et al., 1996),

OGT are used

- in hospital for the treatment of pressure ulcers,
- in podiatry for the treatment of hyperkeratoses of the foot,
- in angiology-phlebology for the treatment of varicose ulcers and in the composition of venotonic cream s,
- in dermatology for the treatment of male androgenic alopecia,
- in cosmetology in the composition of moisturizing creams.

Clinical trial

A hospital-based clinical trial was conducted in the context of the specialized outpatients department for the Complete Removable Dentures University Diploma (Rangueil Dentistry Department – Toulouse Hospital – Head of Department: Prof. J. Ph. Lodter) and in private patients. Patients were selected regardless of their age, their prosthetic history and their general state of health.

Objective

This clinical trial was designed to verify the efficacy and relevance of an OGT dental gel in totally edentulous patients with complete removable dentures:

- objective signs: improvement of clinical signs (pain, inflammation, etc.).
- subjective symptoms: improved comfort when wearing dentures.

Material

The patients were provided with two tubes of gel, sufficient for two weeks of treatment.

Patients were instructed to apply a very small quantity of gel onto the lining of their dentures, after cleaning them with water, two to three times a day according to the patient's habits. The patient was asked not to use any mouthwash solutions or detergents during this period.

Method

At the first visit, the local clinical state of the patient's mucosa was evaluated according to the Budtz-Jørgensen classification. Type 0 corresponds to the absence of pathological signs.
At a second visit (2 weeks later), the local clinical state was re-evaluated according to the same criteria.
The patient's comments were recorded:

- efficacy on pain,
- comfort and feeling of well-being provided by the gel,
- compliance with treatment (frequency and conditions of application),
- have-you observed an improvement? If yes, was this improvement obtained immediately after application, several minutes later, after a longer interval? Did this improvement persist for a long time?
- would you like to continue using this gel?

Population

- Number of patients:

A total of 39 patients were included in the trial, distributed as follows:
- 17 patients in the Dentistry Department, Rangueil Hospital, Toulouse University Hospitals System
- 22 patients in private dentistry practices.

Two patients dropped out of the protocol (problems of general health, hospitalisation).

- Gender:

There were 29 women and 10 men.

- Age:

The age of the patients ranged from 38 to 92 years with a mean of 67.5 years for women and 64.5 years for men.

Table 1 – Mean age of the patients

Mean age	40 years	50 years	60 years	70 years	80 years	90 years
Men	2		2	5	1	
Women	1	4	7	8	7	2

- General state of health of the patients:

Table II – General state of health of the patients

State of health	Excellent	Good	Moderate	Poor
Men	7	1		2
Women	16	3	5	5

- Patient dexterity:

Table III – Patient dexterity

Dexterity	Good	Poor

Men	10	0
Women	24	5

- Patient's prosthetic status

8 patients were fitted with new dentures.
12 patients were fitted with dentures requiring several modifications.
17 patients were fitted with dentures not requiring any modification.

Results

The frequency of applications was twice daily for 12 patients and 3 times daily for 25 patients. Two groups of patients can be distinguished:

Group 1: 8 patients fitted with new dentures

- Local clinical evaluation:

The patients could not be classified according to the Budtz-Jørgensen classification.
Three of these patients had recently undergone complete dental extraction: following the last extractions, they therefore wore complete dentures for the first time. Very good healing was seen (despite the presence of periodontal disease and diabetes). There was no postoperative pain, and no systemic medication was required. Temporary complete dentures were perfectly integrated in these 3 patients.
New dentures were fitted in 5 patients. Integration was obtained by the first week with no wounds and no ulceration.

- Evaluation by the patient:

The gel was very effective on pain for all patients and provided comfort and a feeling of well-being for 6 patients; while 2 patients did not express any opinion.
Four patients expressed a desire to continue application of the gel.
Two patients did not wish to continue this treatment, one patient did not know and another patient only applied the gel during healing.

Group 2: 29 patients already fitted with dentures

- Local clinical evaluation:

These patients were classified into 4 groups according to the Budtz-Jørgensen classification:

- *Type 0*: 3 patients (Fig. 5 and 6)

Two patients were very elderly (88 and 92 years old) and 1 patient was anorexic. An improvement of the texture and tone of the mucous membranes was observed. This improvement was observed by the first week.

- *Type 1*: 13 patients (Fig. 7)

Six patients described discomfort and diffuse pain, 4 patients had a thin mucosa with several ulcerations, 2 patients had poor oral hygiene, and 1 patient suffered from moderately dry mouth. Progressive improvement towards type 0 was observed.

- *Type 2*: 6 patients (Fig. 8)

Five patients with poorly fitting dentures reported discomfort and diffuse pain, 1 patient suffered from dry mouth.
A rapid improvement towards type 0 was observed by the first week of application of the gel.

- *Type 3*: 7 patient (Fig. 9)
All 7 patients described discomfort and permanent pain. Two patients had fissured hyperplasia, 1 patient had papillary hyperplasia, and 1 patient reported severe dry mouth, with associated oropharyngeal candidiasis, which was treated concomitantly and specifically.
An improvement towards type 1 was observed after 2 weeks of application. Improvement towards type 0 was obtained after 1 month of application (at the patients' request).

- Evaluation by the patient:
- 24 patients considered the gel to be very effective on pain and discomfort;
- 24 patients considered that the gel provided comfort and a feeling of well-being: "I feel better after applying the gel", "my gums no longer feel so tight", "my gums are not so tired at the end of the day";
- 27 patients reported an improvement immediately after application that lasted several hours;
- 19 patients expressed the desire to continue application
- 3 patients expressed the desire to continue application in the case of pain or injury;
- 7 patients did not wish to continue application.

Table IV – Patient's intention to continue treatment

	Type 0	Type 1	Type 2	Type 3
Would like to continue treatment	1	7	4	7
Would like to continue in the case of pain or injury	0	2	1	0
Does not want to continue	2	4	1	0

Discussion

For the 8 patients with new dentures, application of the gel constituted an effective aid to the management of postoperative pain and for integration of the dentures. However, it is unfortunate that only one half of the patients realised the necessity of maintenance of their oral mucosa and expressed the desire to continue application of the gel.

For the 29 patients already fitted with dentures, regardless of the good or poor fit of their dentures, regular application of the gel led to relatively rapid resolution of the clinical signs of denture stomatitis (1 to 2 weeks for types 1 and 2, 1 month for type 3). The high pH of the gel probably tended to modify local conditions by increasing the local acid pH, which constitutes a predisposing and aggravating factor for denture stomatitis.

Twenty four patients reported the efficacy of the gel: efficacy on pain and healing of lesions, improvement of comfort and a feeling of well-being.

The two oldest patients were unable to express an opinion on the efficacy and improvement provided by the gel. These patients, classified as type 0 at the first visit, did not feel the need to continue treatment. Application of the gel allowed 19 patients to realise the need for maintenance of their oral mucosa, as they expressed the desire to continue application despite resolution of the clinical signs. The 7 patients presenting the most severe lesions all recognized the efficacy of the gel and the need to continue treatment.

Conclusion

This preliminary study was based on a sample of totally edentulous patients fitted with removable dentures of various ages and presenting with various states of general health, with and without signs of denture stomatitis.

It demonstrates the efficacy and relevance of using an oxygenated glycerol triester gel in the great majority of these patients.

The new concept of a specific treatment for patients with removable dentures appears to be very interesting both for patients who are able to ensure daily oral hygiene and for practitioners who can improve wearing and integration of dentures.

Figures

Fig. 1. Recently edentulous patient fitted with dentures. Note the perfectly healthy mucosa.

Fig. 2. Budtz-Jørgensen classification. Type 1: simple localized inflammation.

Fig. 3. Budtz-Jørgensen classification. Type 2: simple generalized inflammation.

Fig. 4. Budtz-Jørgensen classification. Type 3: inflammatory papillary hyperplasia. Note the presence of fissured hyperplasia (Photograph: Dr Michel Dabadie).

Fig. 5. Type 0: very elderly patient (90 years) presenting with perfectly healthy mucosa despite severe bone resorption.

Fig. 6. Type 0: another patient with normal support surface.

Fig. 7. Budtz-Jørgensen classification Type 1: simple localized inflammation.

Fig. 8. Budtz-Jørgensen classification. Type 2: simple diffuse inflammation.

Fig. 9. Budtz-Jørgensen classification. Type 3: inflammatory papillary hyperplasia.